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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Shubh D. Sharma

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10/10/2006

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EXAMINER:

GUPTA, ANISH

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 10/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

5#

Office Action Summary	Application No. 10/756,212	Applicant(s) SHARMA ET AL.	
	Examiner Anish Gupta	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-34 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 10, 12, 14, 33-34, drawn to a polypeptide comprising sequence Ser-Phe-Arg-Trp, classified in class 514, subclass 2+.
- II. Claim 10, 12, 14 drawn to a polypeptide comprising the sequence Ser-Phe-Arg-Nal, classified in class 514, subclass 2+.
- III. Claims 10, 12, 14, drawn to a polypeptide comprising the sequence ala-phe-arg, classified in class 514, subclass 2+.
- IV. Claim 10, 12, 14 drawn to a polypeptide comprising the sequence Thr-Phe-Arg-Trp, classified in class 514, subclass 2+.
- V. Claims 10, 12, 14, drawn to a polypeptide comprising the sequence Ser-Nal-Arg-Trp, classified in class 514, subclass 2+.
- VI. Claim 10, 12, 14 drawn to a polypeptide comprising the sequence Ala-Nal-Arg-Trp, classified in class 514, subclass 2+.
- VII. Claims 15-22, drawn to a melanocortin receptor specific linear peptide, classified in class 514, subclass 2+.
- VIII. Claim 23-28, drawn to a cyclic peptide, classified in class 514, subclass 9.
- IX. Claims 29-32, drawn to a method of stimulating sexual response in a mammal, classified in class 514, subclass 2+.

The inventions are distinct, each from the other because of the following reasons:

Claims 1-9, 11, 13 link(s) inventions Groups I-VI. The restriction requirement between the linked inventions is **subject to** the nonallowance of the linking claim(s), claim 1-9, 11, 13. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked

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inventions **shall** be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 **Claims that require all the limitations of an allowable linking claim** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Note that the peptides of claims 1-14 have been separated based on their core structures. Thus, those peptides having the core sequence Ser-Phe-Arg-Trp have been group together. This is similarly true of the peptides of Groups II-VI.

The peptides of Group I-VI have been separated and are independent and distinct because of their independent structure. The sequence Ser-Phe-Arg-Trp is structurally distinct from the sequence Ala-Nal-Arg-Trp, which is structurally separate from Ser-Phe-Arg-Nal. The peptide of Group VII are independent and distinct from the peptides of Group I-VI because the peptides of Group VII require the presence of variables R2 and R3 that are not present in the peptides of Group I-VI. The peptides of Group VIII are structurally distinct from the other groups as result of the cyclic bridge. The linkage between the carbonyl end and the amino side chain deletes the

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variable R1 in Group VII and terminal hydrogen in Group I-VI. Due to the structural distinction in each group, the peptides are independent and distinct from one another.

The search for each peptide would be burdensome because each would required a separate search. The search of the peptide comprising Ser-Phe-Arg-Trp would be separate than a search for cyclic peptides and peptide having the sequence Ala-Nal-Arg-Trp.

Inventions Group I-VIII and Group IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case a method of stimulating sexual response can be achieve by peptides such as Nle-Alsp-His-D-Phe-Arg-Trp-Lys (see US5576290).

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

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Claims 1-9, 11, 13, 15-32 are generic to the following disclosed patentably distinct species:

Species listed in claims 10, 12, 14, 33-34

For any Group elected, Applicants are requested to elect a single disclosed species. Thus, if Applicants elect Group IV, then Applicants should elect a variant Thr-Phe-Arg-Trp that has specific substitution on the N-terminal end of the peptide and the side chains. As an example, the generic peptide of Group I has 10 corresponding species in claim 10 (the first 10 sequences). Thus, Applicants are requested to elect a single disclosed species for any of the Groups elected.

The species are independent or distinct because they are structurally distinct from one another. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and

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specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (571)272-0965. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can normally be reached on (571) 272-0562. The fax phone number of this group is (571)-273-8300.


Anish Gupta
Patent Examiner